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zimmer

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

JUL - 1 2011

Summary of Safety and Effectiveness

Sponsor:

Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

Contact Person:

Mark D. Warner
Specialist, Regulatory Affairs
Telephone: 574-372-4150
Fax: (574) 372-4605

Date:

April 1, 2011

Trade Name:

Zimmer® Segmental System *Trabecular Metal*™ Proximal Tibial Component, *Trabecular Metal* Proximal Femoral Component, and additional Segment with Male/Female Taper components

Common Name:

Total Hip Prosthesis (proximal femoral component, segment components)

Total Knee Prosthesis (proximal tibial component, segment components)

Classification Name and Reference:

LPH - Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented; 21 CFR § 888.3358

LWJ - Prosthesis Hip, Semi-Constrained, Metal/Polymer, Uncemented; 21 CFR § 888.3360

JDI - Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented; 21 CFR § 888.3350

LZO - Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented; 21 CFR § 888.3353

KWY - Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented or Uncemented; 21 CFR § 888.3390

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KWL - Prosthesis, Hip, Hemi-, Femoral, Metal; 21 CFR § 888.3360

KWZ - Prosthesis, Hip, Constrained, Cemented or Uncemented, Metal/Polymer; 21 CFR § 888.3310

KRO - Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/Polymer; 21 CFR § 888.3510

Predicate Devices:

Zimmer Segmental System, manufactured by Zimmer Inc. (K070978, cleared July 3, 2007)

Zimmer Segmental System Proximal Femoral Component, manufactured by Zimmer Inc. (K101296, cleared July 30, 2010)

MOST System, manufactured Intermedics Orthopedics, Inc. (K964350, cleared January 16, 1997)

MOST Options System, manufactured Sulzer Orthopaedics (K013031, cleared December 7, 2001)

NexGen® Complete Knee Solutions Rotating Hinge Knee System, manufactured by Zimmer, Inc. (K013385, cleared January 9, 2002)

Device Description:

The *Zimmer* Segmental System is intended to replace the proximal femur, mid-shaft femur, distal femur, proximal tibia and/or total knee in cases that require extensive resection and restoration. The Segmental System provides for cross compatibility between selected components from the *MOST Options*® System and *NexGen*® Rotating Hinge Knee System. A total mid-calf to hip replacement can be achieved using the Segmental System. The cleared distal femoral component and the proposed proximal tibial component are designed to be compatible with standard *NexGen* patella components. The proximal femoral components are designed to be compatible with various Zimmer femoral heads with a 12/14 taper.

The *Trabecular Metal* Proximal Femoral Component is designed to replace the proximal femur and is available in two sizes (38mm and

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46mm offsets). The *Trabecular Metal* Proximal Tibial Component is designed to replace the proximal tibia and is available in three sizes. The Segment with Male/Female Taper components are designed to be used with Segmental System Stem Extensions in combination with a proximal femoral component, a distal femoral component, and/or a proximal tibial component, or intercalary segments, in order to replace portions of the proximal femur, mid-shaft femur, distal femur, and/or proximal tibia.

Intended Use:

This Segmental System is indicated for:

- Moderate to severe knee instability
- Significant bone loss and/or ligament deficiencies caused by neoplasms, trauma, rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, and/or avascular necrosis of the proximal and/or distal femur and/or proximal tibia
- Valgus, varus or flexion deformities
- The salvage of previously failed surgical attempts

- A total femoral replacement construct consisting of the *MOST Options* or Segmental proximal femoral, Segmental System segments and Segmental System distal femoral components may be used without cement.
- Variable Stiffness stem extensions require the use of either a smooth or *Trabecular Metal* stem collar, which must be cemented to the stem. Following cementing to the stem, the smooth collar must be cemented against the bone. The remainder of the stem must be used uncemented.
- Fluted stem extensions require the use of either a smooth or *Trabecular Metal* stem collar, which must be cemented to the stem. Following cementing to the stem extension, the smooth collar must be cemented against the bone. The remainder of the stem must also be cemented against the bone.
- The *Trabecular Metal* collar may be used cemented or uncemented against the bone.
- All other constructs are for cemented use only.

Comparison to Predicate Device:

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The proposed Segmental System components are similar or identical in intended use, materials, sterility, and performance characteristics to the predicate devices.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

The results of non-clinical (lab) performance testing demonstrate that the devices are safe and effective and substantially equivalent to the predicate devices. Performance testing included: proximal femoral component fatigue test, proximal tibial component fatigue test, segment component fatigue test.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Zimmer, Inc.
% Mr. Mark D. Warner
Specialist, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

JUL - 1 2011

Re: K110940
Trade/Device Name: *Zimmer* Segmental System *Trabecular Metal* Proximal Tibial Component, *Trabecular Metal* Proximal Femoral Component, and additional sizes of Male-Female Segments
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: II
Product Codes: KRO; LZO, JDI, LPH, LWJ, KWZ, KWL, KWY
Dated: April 1, 2011
Received: April 4, 2011

Dear Mr. Warner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110940

Device Name:

Zimmer Segmental System *Trabecular Metal* Proximal Tibial Component, *Trabecular Metal* Proximal Femoral Component, and additional Segment with Male/Female Taper components

Indications for Use:

- This device is indicated for:
  - Moderate to severe knee instability
  - Significant bone loss and/or ligament deficiencies caused by neoplasms, trauma, rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, and/or avascular necrosis of the proximal and/or distal femur and/or proximal tibia.
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- All other constructs are for cemented use only.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line -- Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110940